Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of resistance training on women's bone parameters, before and after menopause

Protocol summary

Study aim
Comparison of the effect of resistance training on bone mineral density and bone mineral content and bone youth index and bone age and bone area adaptation of postmenopausal and non-menopausal women with osteopenia

Design
A clinical trial with a control group with parallel blind groups is randomly assigned to 40 people with osteopenia. A lottery was used for randomization.

Settings and conduct
Subjects were selected from the Endocrine and Metabolism Research Center of the Red Crescent Subspecialty and Physical Rehabilitation Center And after examination by an endocrinologist and referral to the researcher has completed the consent and personal information And they start training at the Red Crescent Rehabilitation Center.

Participants/Inclusion and exclusion criteria
Age range 40 to 60 years Menopausal and non-menopausal women with osteopenia with body mass index between 18 to 25 No history of hormone therapy No use of any hormonal drugs during treatment No history of joint disease No history of any fractures or surgery

Intervention groups
In the experimental groups (menopause and non-menopause), resistance training due to individual differences, the intensity of training was 70 to 85% 1RM. The number of repetitions also changed from 8 repetitions to 12 repetitions from the first to the fourth month. It is 60 minutes, the researcher monitored the exercises throughout the duration, the control group did not intervene during these 4 months and continued their daily life.

Main outcome variables
Independent variable: resistance training Dependent variables: bone mineral density, bone mineral content, T score, Z score,Bone area

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211017052792N1**
Registration date: **2021-11-13, 1400/08/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-13, 1400/08/22**
Update count: **0**

Registration date
2021-11-13, 1400/08/22

Registrant information

Name
Fatemeh Ghorbani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3340 5980

Email address
lotfi@bondagroup.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of resistance training on women's bone parameters, before and after menopause

Public title

The effect of resistance training on improving bone mineral density

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Postmenopausal and non-menopausal women in the age range of 40 to 60 years with osteopenia approved by an endocrinologist weight in the normal range and with a body mass index between 18 and 25 according to the criteria of the World Health Organization

Exclusion criteria:

Any fractures or surgery on the lower limbs and spine hormone intake that affects bone tissue metabolism pre-hormone therapy and exercise in the past 6 months and during the study period people with joint diseases such as osteoarthritis and osteoarthritis In the lower limbs

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study consists of 4 postmenopausal groups (intervention and control) and non-menopausal group (intervention and control). We use the classification randomization method to randomize the sample selection. In this method, participants are placed in two classes A and B based on menopausal status factor (menopause and non-menopause) and then in each class, simple randomization (lottery) is used to select samples for the intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, blindness is one-sided and due to the fact that the researcher interviews individuals personally and after the study description and obtaining written consent, puts them under medical intervention or control group, the researcher assigns individuals and groups. It is aware and only patients do not know which group they belong to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Tehran

Street address

Daneshjoo Blvd,Shahid Shahriari Square,Yemen St.,Chamran Highway,Tehran,Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2021-04-26, 1400/02/06

Ethics committee reference number

IR.SBU.REC.1400.009

Health conditions studied

1

Description of health condition studied

Decreased bone density in postmenopausal and non-menopausal women

ICD-10 code

M81.0

ICD-10 code description

Age-related osteoporosis without current pathological fracture

Primary outcomes

1

Description

The effect of exercise on bone mineral density

Timepoint

Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.

Method of measurement

Bone Density Tester

2

Description

The effect of exercise on bone mineral content

Timepoint

Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.

Method of measurement

Bone Density Tester

3

Description
The effect of exercise on bone Z- score
Timepoint
Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.
Method of measurement
Bone Density Tester

4

Description
The effect of exercise on bone T-score
Timepoint
Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.
Method of measurement
Bone Density Tester

5

Description
The effect of exercise on bone area
Timepoint
Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.
Method of measurement
Bone Density Tester

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Due to individual differences and a maximum repetition, ie the maximum weight that a person can move for one time, resistance exercises with dumbbells with an intensity of 70 to 85% of a maximum repetition and 8 to 12 repetitions on the extensor muscles of the trunk and front muscles.And the back of the foot is done for 4 months. It should be noted that the duration of the exercises, taking into account warm-up and cooling, is 60 minutes.
Category
Treatment - Other

2

Description
Intervention group 2 (non-menopausal group): Non-menopausal group such as menopausal group due to individual differences and a maximum repetition means the maximum weight that a person can move for one time. And 8 to 12 repetitions are done on the extensor muscles of the trunk and the muscles of the front and back of the leg for 4 months. It should be noted that the duration of the exercises is 60 minutes, taking into account warm-up and cooling.
Category
Treatment - Other

3

Description
Control group: The postmenopausal control group and the non-menopausal control group resume their normal daily activities for 4 months and avoid taking bone density medication.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Red Crescent Rehabilitation Center
Full name of responsible person
Fatemeh Ghorbani
Street address
Red Crescent Comprehensive Rehabilitation Center,next to Khatam Al-Anbia Hospital,Rashid Yasemi St.,above Mirdamad,Valiasr St.,Tehran,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University
Full name of responsible person
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Blvd. Student,Shahid Shahriari Square,Yemen St.,Shahid Chamran Highway
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pr.ac.sbu.mail@office

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Fatemeh Ghorbani
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available